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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,614	01/28/2004	Lawrence A. Shimp	525400-332	3427

7590 12/08/2006

WILLIAM SQUIRE, ESQ.  
C/O CARELLA, BYRNE, BAIN, GILFILLAN,  
CECCHI, STEWART & OLSTEIN  
5 BECKER FARM ROAD  
ROSELAND, NJ 07068

EXAMINER

MCKANE, ELIZABETH L

ART UNIT PAPER NUMBER

1744

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/766,614

Applicant(s)

SHIMP ET AL.

Examiner

Leigh McKane

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,9-11,13-23,25,27,30-39 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,9-11,13-23,25,27,30-39 and 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>012804, 081304</u> | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In lines 5-7, the phrase “solution is flowed continuously to and away from the centrifuge containing the tissue to produce a G force on the material” is confusing as it is the centrifuging that produces the G force, not the flowing of the solution.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 25, 30-32, 44, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolfinbarger, Jr. et al. (US 5,977,432).

Wolfinbarger, Jr. et al. teaches a process for inactivating and reducing pathogens in a bone tissue **13** having a longitudinal axis and a plurality of cavities. The longitudinal axis of graft **13** is the axis of the graft which has a length dimension that is greater than its other dimensions. The process includes centrifuging the tissue in a centrifuge with a pathogen solvent. See col.4, lines 21-34. The centrifuging will produce a G force on the graft in a direction parallel

Art Unit: 1744

to the longitudinal axis of the graft **13**. After treatment with the solvent, the bone is dry spun (col.13, lines 46-48). The solvent is selected from alcoholic solutions, detergent solutions, antibiotic solutions, antiviral solutions, etc.. See col.4, line 56 to col.5, line 3.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 2, 4, 6, 9-11, 13-18, 27, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfinbarger, Jr. et al. (US 5,977,432) in view of Wolfinbarger, Jr. (US 5,976,104).

With respect to claims 1, 2, 4, 10, 11, 13-18, and 46, Wolfinbarger, Jr. et al. teaches a process for inactivating and reducing pathogens from a tissue (bone) having a plurality of cavities. The process includes centrifuging the tissue in a centrifuge with a pathogen solvent. See col.4, lines 21-34. The solvent is selected from alcoholic solutions, detergent solutions,

antibiotic solutions, antiviral solutions, etc.. See col.4, line 56 to col.5, line 3. After treatment with the solvent, the bone is dry spun (col.13, lines 46-48). Wolfinbarger, Jr. et al. also discloses that “if the amount of lipid material to be solubilized exceeds the solubilization capability of the detergent present, lipid solubilization will not be complete.” To this effect, Wolfinbarger, Jr. et al. suggests that by “continually changing the detergent solution over time, it becomes possible to completely solubilize all solubilizable lipid present in a bone graft.” See col.8, lines 5-10.

Wolfinbarger, Jr. (‘104) teaches in another method of bone treatment the continual replacement of solvent which reduces the need for greater concentrations of solubilization enhancing components. See col.2, lines 25-29. In the invention of Wolfinbarger, Jr. the solvent solution is flowed continuously to and away the treatment chamber.

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a means to continuously introduce to and remove solvent from the centrifuge of Wolfinbarger, Jr. et al., for the reasons cited by both Wolfinbarger, Jr. et al. and Wolfinbarger, Jr. – that is, to completely solubilize all solubilizable lipids present and to reduce the need for greater concentrations of solubilization enhancing components.

As to claim 6, it is deemed obvious to one of ordinary skill in the art to choose an appropriate volume of solvent to employ based upon known parameters such as tissue size, centrifuge chamber size, and the amount of pathogen material present.

With respect to claims 9 and 27, Wolfinbarger, Jr. et al. discloses at 2500 rpm the G force is 1657. See col.12, lines 23-24. Using the equation used by Wolfinbarger, Jr. et al. to convert centrifuge rpm to G force (col.6, line 12) and the disclosed rpm range of Wolfinbarger, Jr. et al. yields a G force range of 247.5 to 6188 for centrifuge rotational speeds of 1000-5000 rpm.

8. Claims 19, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfinbarger, Jr. et al. and Wolfinbarger, Jr. as applied to claims 18 and 17 above, and further in view of Morris et al. (WO 01/58497).

As to claim 19, while Wolfinbarger, Jr. et al. does teach infusing the bone with an antibiotic, the infusion of a growth factor is not disclosed. Morris et al. discloses that it was known in the art to sterilize and impregnate with growth factor bone intended for transplantation. See page 1, first paragraph. It would have been obvious to use the method of Wolfinbarger, Jr. et al. to impregnate the bone with growth factor since Morris et al. teaches that doing so prepares the bone for a successful transplantation.

With respect to claims 22 and 23, Wolfinbarger, Jr. et al. is silent with respect to infusing the bone with a polymer. However, Morris et al. teaches the known infusion of bone with medically useful polymers, such as polymer cell scaffolds, polymeric carriers containing drugs, and bioerodable polymers. See page 9, lines 20-22 and page 10, lines 9-10. As these types of polymers are capable of promoting tissue growth and/or dispensing drugs *in vivo*, it would have been obvious to use the method of Wolfinbarger, Jr. et al. to infuse the bone with these polymers.

9. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfinbarger, Jr. et al. (hereinafter 'Wolfinbarger '432') and Wolfinbarger, Jr. as applied to claim 17 above, and further in view of Wolfinbarger, Jr. et al. (US 6,293,970, hereinafter 'Wolfinbarger '970').

Wolfinbarger '432 fails to teach infusing the bone with a plasticizer. Wolfinbarger '970 discloses a process of sterilizing a bone graft followed by infusion with a plasticizer, such as glycerol. See col.7, line 42. The plasticizer is effective in improving graft brittleness and

removes the necessity of graft rehydration prior to implantation. For these reasons, it would have been obvious to use the method of Wolfinbarger '432 to infuse the bone graft with a plasticizer.

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfinbarger, Jr. et al. (US 5,977,432).

Wolfinbarger, Jr. et al. discloses at 2500 rpm the G force is 1657. See col.12, lines 23-24. Using the equation used by Wolfinbarger, Jr. et al. to convert centrifuge rpm to G force (col.6, line 12) and the disclosed rpm range of Wolfinbarger, Jr. et al. yields a G force range of 247.5 to 6188 for centrifuge rotational speeds of 1000-5000 rpm. Thus, it would have been obvious to use a G force of at least 2000 G in the method of Wolfinbarger, Jr. et al., as this range is within that disclosed by Wolfinbarger, Jr. et al..

11. Claims 33, 36, 37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfinbarger, Jr. et al. (US 5,977,432) in view of Morris et al. (WO 01/58497).

As to claim 33, while Wolfinbarger, Jr. et al. does teach infusing the bone with an antibiotic, the infusion of a growth factor is not disclosed. Morris et al. discloses that it was known in the art to sterilize and impregnate with growth factor bone intended for transplantation. See page 1, first paragraph. It would have been obvious to use the method of Wolfinbarger, Jr. et al. to impregnate the bone with growth factor since Morris et al. teaches that doing so prepares the bone for a successful transplantation.

With respect to claims 36, 37, and 39, Wolfinbarger, Jr. et al. is silent with respect to infusing the bone with a polymer. However, Morris et al. teaches the known infusion of bone with medically useful polymers, such as polymer cell scaffolds, polymeric carriers containing

Art Unit: 1744

drugs, and bioerodable polymers. See page 9, lines 20-22 and page 10, lines 9-10. As these types of polymers are capable of promoting tissue growth and/or dispensing drugs *in vivo*, it would have been obvious to use the method of Wolfinbarger, Jr. et al. to infuse the bone with these polymers.

12. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfinbarger, Jr. et al. (US 5,977,432, hereinafter 'Wolfinbarger '432') in view of Wolfinbarger, Jr. et al. (US 6,293,970, hereinafter 'Wolfinbarger '970').

Wolfinbarger '432 fails to teach infusing the bone with a plasticizer. Wolfinbarger '970 discloses a process of sterilizing a bone graft followed by infusion with a plasticizer, such as glycerol. See col.7, line 42. The plasticizer is effective in improving graft brittleness and removes the necessity of graft rehydration prior to implantation. For these reasons, it would have been obvious to use the method of Wolfinbarger '432 to infuse the bone graft with a plasticizer.

13. Claims 38 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfinbarger, Jr. et al. (US 5,977,432) in view of Morris et al..

Wolfinbarger, Jr. et al. teaches a method of centrifuging bone in order to remove contaminants therefrom while impregnating the bone with decontaminating agents, antibacterial agents, antibiotics, etc.. See col.6, line 15 to col.7, line 7. Wolfinbarger, Jr. et al. does not disclose impregnating the bone with a growth factor. Morris et al. discloses that it was known in the art to sterilize and impregnate with growth factor bone intended for transplantation. See page 1, first paragraph. It would have been obvious to use the method of Wolfinbarger, Jr. et al. to



impregnate the bone with growth factor since Morris et al. teaches that doing so prepares the bone for a successful transplantation.

14. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfinbarger, Jr. et al. (US 5,977,432) in view of Peterson (US 5,730,933).

Wolfinbarger, Jr. et al. teaches a method of centrifuging bone in order to remove contaminants therefrom while impregnating the bone with decontaminating agents, antibacterial agents, antibiotics, etc.. See col.6, line 15 to col.7, line 7. Wolfinbarger, Jr. et al. does not disclose impregnating the bone with a radiation protectant. Peterson teaches that it was known in the art at the time of the invention to use radiation to sterilize bone before use and to add a radiation protectant (scavenger) to the bone before irradiation thereof. See Abstract; col.3, line 45; col.4, lines 36-51. It would have been obvious to add the radiation protectant of Peterson to the bone of Wolfinbarger, Jr. et al. for subsequent sterilization since Peterson teaches that radiation sterilization offers a level of sterility unmatched by conventional methods and that the scavenger protects the bone from free radicals during sterilization. Moreover, one would have found it obvious to add a radiation protectant to the bone of Wolfinbarger, Jr. et al. during centrifuging, as Wolfinbarger, Jr. et al. teaches that the process of centrifuging is effective in moving fluids into and out of bone.

#### ***Claim Objections***


15. Claim 4 is objected to because of the following informalities: In line 3, “lips” should be --lipids--. Appropriate correction is required.

***Conclusion***

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
6 December 2006